In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 18-627V Filed: April 12, 2021 PUBLISHED

SHERRI PAIGE,

Petitioner,

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SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Master Horner

Finding of Fact; Influenza Vaccination; Vaccination Record; Date of Vaccination

Bridget Candace McCullough, Muller Brazil, LLP, Dresher, PA, for petitioner. Mary Eileen Holmes, U.S. Department of Justice, Washington, DC, for respondent.

FINDING OF FACT¹

On May 2, 2018, petitioner, Sherri Paige, filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012), alleging that she suffered transverse myelitis ("TM") resulting from adverse effects of an influenza ("flu") vaccination she received while at work as a nurse at Generations Family Health on October 9, 2015. (ECF No. 1, p. 1.) Although petitioner alleged a vaccination date of October 9, 2015, her petition was accompanied by an employee vaccine administration record filed as Exhibit 1 which reflected a vaccination date of November 11, 2015. (Ex. 1, p. 1.)

On November 24, 2020, petitioner moved for a ruling on the record finding that petitioner did receive her 2015 flu vaccination on October 9, 2015 as she alleged. (ECF No. 72.) However, for the reasons discussed below, I find that petitioner more likely than not received her vaccination on November 11, 2015 as reflected in her contemporaneous vaccine administration form.

¹ Because this finding contains a reasoned explanation for the special master's action in this case, it will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. See 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). This means the finding will be available to anyone with access to the Internet. In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information the disclosure of which would constitute an unwarranted invasion of privacy. If the special master, upon review, agrees that the identified material fits within this definition, it will be redacted from public access.

I. Procedural History

In the affidavit accompanying her petition, petitioner explained the circumstances of her vaccination as follows:

I received the influenza vaccination on October 9, 2015. At the time of the vaccination, I was employed at Generations Family Health Clinic, Inc. . . . On that date, my supervisor administered the vaccination while we were operating a mobile health clinic. The paperwork documenting my vaccination was completed two days later on October 11, 2015.

(ECF No. 1-13; Ex. 8, p. 1.)

Respondent filed his Rule 4 Report on April 29, 2019, along with a motion to dismiss.² (ECF No. 23.) Respondent noted the discrepancy between the date of vaccination alleged in the petition and the date reflected on petitioner's vaccination record. He contended that petitioner's vaccination could not be the cause of her injury because her symptoms began in early October and the correct date of vaccination was November 11, 2015 rather than October 9, 2015. (*Id.* at 2, 10.)

In response, petitioner sought and received authorization to subpoena Generations Family Health for petitioner's employment records. (ECF Nos. 25-26.) Those records were later filed on June 3, 2019. (ECF No. 30; Ex. 14.) In the interim, petitioner also filed a copy of a text message from her supervisor, Nicole Jones, discussing petitioner's efforts to obtain documentation of her flu vaccination and referencing the date of vaccination as "10/9/15." (ECF No. 28; Ex. 13.)

Petitioner was then provided further opportunity to investigate her allegation regarding the date of her vaccination and subsequently filed a further affidavit. (ECF No. 35; Ex. 15.) She also received authorization to serve a further subpoena upon Generations Family Health for records relating to the mobile health clinic at which she alleged her vaccination was administered. (ECF Nos. 33, 36.) Additionally, petitioner sought to subpoena T-Mobile for further documentation of the previously filed text message with Nicole Jones. (ECF Nos. 37-38.)

This case was reassigned to me on August 27, 2019. (ECF NO. 41.) Petitioner subsequently filed responses from the two outstanding subpoenas on September 30, 2019. In response to the second subpoena, Generations Family Health reproduced portions of petitioner's employment file. (ECF No. 42-1; Ex. 16.) T-Mobile advised that they do not store or maintain the contents of text messages and did not otherwise produce any relevant records. (ECF No. 42-2; Ex. 17.)

On November 19, 2019, petitioner filed an e-mail from the director of human resources at Generations Family Health. (ECF No. 44; Ex. 18.) It confirmed that petitioner had worked on the mobile health clinic with Ms. Jones on October 9, 2015,

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² The motion to dismiss was later withdrawn. (ECF No. 46.)

but indicated that Ms. Jones would not be made available for any informal conversation regarding the matter. (*Id*.)

I held a follow up status conference on November 21, 2019. (ECF No. 45.) I noted that the question of the date of petitioner's vaccination implicates the circumstances of both October 9, 2015, and November 11, 2015. I suggested that petitioner seek time and attendance records for both petitioner and Nicole Jones for October and November of 2015. I also suggested that the parties depose both petitioner and Ms. Jones. (*Id.*)

Deposition transcripts were filed on March 19, 2020. (ECF No. 58 (Paige Deposition as Exhibit 24 and Jones Deposition as Exhibit 25).) A follow up status conference was held on April 16, 2020. (ECF No. 62.) During that status conference, the parties discussed two additional lines of inquiry. First, during her deposition petitioner identified an additional witness, Ingrid Aldrige, who was allegedly present when the vaccination record at issue was created. Second, testimony suggested that Generations Family Health may be able to identify the dates on which doses from the multidose vial identified on petitioner's vaccination record were administered.

On July 26, 2020, petitioner filed responses to interrogatories from Generations Family Health and an affidavit by Ingrid Aldridge. (ECF No. 68; Exs. 41-42.) I subsequently required the parties to file a joint status report indicating how they propose to proceed. The parties advised in a status report filed August 19, 2020, that "[t]he parties have conferred and respectfully request that the Special Master resolve the factual issue of petitioner's vaccination date by a ruling on the record." (ECF No. 69.)

Petitioner filed her motion for a ruling on the record on November 24, 2020. (ECF No. 72.) Respondent filed his response on January 25, 2021. (ECF No. 73.) Petitioner filed no reply. Accordingly, the motion is ripe for resolution.

II. Factual History⁴

A. As reflected in petitioner's medical records

During the relevant period, petitioner received her primary healthcare through Generations Family Health Center, which was also her employer. (Ex. 2; Ex. 14.)

³ I also determined that the parties have had a full and fair opportunity to present their cases and that it is appropriate to resolve this issue without a hearing. See Vaccine Rule 8(d); Vaccine Rule 3(b)(2); Kreizenbeck v. Secretary of Health & Human Services, 945 F.3d 1362, 1366 (Fed. Cir. 2020) (noting that "special masters must determine that the record is comprehensive and fully developed before ruling on the record.").

⁴ Although I have reviewed the entirety of the record compiled to date, including petitioner's complete medical history and employment file, the factual history discussed in this decision is limited to describing the evidence bearing on the correct date of petitioner's 2015 flu vaccination. In addition to reviewing the transcripts of the two depositions conducted in this case, I have also reviewed the accompanying video recordings.

Petitioner's patient records from Generations Family Health do not include an immunization history. (Ex. 2, p. 18.) Prior to the period at issue, petitioner was last seen by her primary care provider, Family Nurse Practitioner Erica Lyons, on June 18, 2015. (Ex. 2, pp. 19, 70.) At that time, she had a follow up on her diabetes and transitioned to Nurse Practitioner Lyons's care. (*Id.*)

Petitioner was next seen by Nurse Practitioner Lyons on November 4, 2015. (Ex. 2, pp. 66-69.) This encounter follows both the October 9, 2015 date of vaccination and October 16, 2015 date of onset of symptoms alleged by petitioner (*Compare* Ex. 2, p. 66 and Ex. 24, pp. 7-9, 14-15), but precedes the date of vaccination reflected in her vaccine administration record (*Compare* Ex. 2, p. 66; Ex. 1). Petitioner's November 4, 2015 encounter was characterized as a follow up appointment. (Ex. 2, p. 66.) No History of Present Illness was recorded⁵; however, petitioner's Review of Systems was positive under musculoskeletal for "[b]ack symptoms and leg symptoms," and under neurological for "[t]ingling of the legs and numbness of the legs." (*Id*.) Petitioner was assessed with bilateral sciatica. (*Id*. at 67.) Petitioner declined medication and a physical therapy referral was provided. (*Id*. at 68.) This record contains no reference to petitioner's vaccination history generally or her alleged October 9, 2015 flu vaccination specifically.

Petitioner returned to Nurse Practitioner Lyons on November 17, 2015. (Ex. 2, pp. 49-55.) At this appointment, petitioner expressed concern regarding possible neurological symptoms and requested an appointment with a neurologist. (Ex. 2, p. 49.) Nurse Practitioner Lyons documented that the prior November 4 encounter had demonstrated only intermittent symptoms consistent with sciatica and no loss of function, saddle paresthesia, gastrointestinal symptoms, or weakness, all of which would have been "red flags." (*Id.*) As of November 17, however, petitioner described increased frequency of symptoms and weakness, but still without loss of function. (*Id.*) Bilateral leg weakness and peripheral neuropathy were added to petitioner's active problems list and petitioner received a referral to neurology as well as an order for x-rays and EMG testing. MRI was not ordered at that time but was "likely needed." (Ex. 2, pp. 49, 54.) This record contains no reference to petitioner's vaccination history generally or to any prior influenza vaccination of any date. Petitioner also had a physical therapy evaluation that day. (Ex. 2, p. 313.) Her vaccination history was not discussed.

Thereafter, petitioner continued to seek care and pursue a diagnosis for the remainder of 2015, throughout 2016, and into 2017. During that period, petitioner returned to Nurse Practitioner Lyons on December 29, 2015, and February 19, 2016. (Ex. 2, pp. 27-29, 39-44.) She consulted multiple neurologists, including Dr. Michelle Boudreau.⁶ (*E.g.* Ex. 2, pp. 194, 210-13 (Dr. Chozick) 280 (Dr. Calderon); Ex. 11 (Dr.

⁵ There is a notation without a heading that indicates "Reviewed and unchanged since last visit." (Ex. 2, p. 66.)

⁶ When petitioner was admitted to the hospital in April of 2016 she had a neurology consult with Dr. Boudreau on April 23, 2016. (Ex. 2, pp. 284-85.) This is the earliest available encounter record by Dr. Boudreau in the record of this case; however, in the record of that consult, Dr. Boudreau indicates that she had previously seen petitioner in her outpatient clinic. (*Id.* at 284.) Dr. Boudreau's own practice

Khan); Ex. 6 (Dr. Boudreau).) She underwent multiple MRIs and an EMG study. (Ex. 2, pp. 54, 310-12; Ex. 6, pp. 48-52, 55-58, 60.) She was hospitalized on two separate occasions, in April of 2016 for IV treatment related to suspected transverse myelitis (Ex. 2, pp. 243-54, 280-93) and in June of 2016 for decompressive laminectomies at T9-T10 (Ex. 2, pp. 194, 210-13). She was subsequently transferred to rehabilitation on both occasions. (Ex. 2, p. 243; Ex. 4, p. 150-51.) She later had a second physical therapy evaluation in January of 2017. (Ex. 5, p. 20.) She saw a gastroenterologist for abdominal pain in early June of 2017, which was assessed as neuropathic pain rather than any gastrointestinal issue. (Ex. 7, p. 59.) Throughout this period petitioner's physicians primarily suspected that petitioner was suffering either a demyelinating condition, such as multiple sclerosis or transverse myelitis, or a degenerative spinal condition. Upon my review, none of petitioner's medical records during this period discuss her vaccination history.

On June 9, 2017, petitioner had a follow up appointment with Dr. Boudreau. (Ex. 6, pp. 19-33.) At this visit, Dr. Boudreau recorded that petitioner "states that when she first had the symptoms in October 2015 she now remembers that she had a flu shot one week prior to this." (*Id.* at 25.) Both parties identify this encounter, more than a year and a half after onset of her condition, as the point at which petitioner began associating her vaccination and injury to her doctors. (ECF No. 72, p. 9; ECF No. 73, p. 8.)

B. As reflected in petitioner's employment records

As noted above, petitioner's employment file contains a vaccine administration record for an influenza vaccination signed and dated November 11, 2015. (Ex. 14, p. 5; Ex. 16, p. 8.) Petitioner filed this record along with her petition as evidence of her vaccination. (Ex. 1.) Timecard records for petitioner produced in connection with the deposition of Nicole Jones confirm that petitioner worked from approximately 7:08AM to 12:38PM on October 9, 2015. (Ex. 34, p. 3.) She worked from approximately 6:44AM to 6:12PM on November 11, 2015.⁷ (*Id.* at 5.) An e-mail from the Generations Family Health Director of Human Resources to petitioner's counsel dated November 1, 2019, further confirms that October 9, 2015 is the only date upon which petitioner worked at the mobile health unit and also that Ms. Jones was also present with petitioner on that date. (Ex. 18.)

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records as produced by Saint Francis Hospital and Medical Center do not include any encounter record from this period. (Ex. 6.) Dr. Boudreau later submitted a report in this case in which she advised that "I am no longer employed by Saint Francis/Trinity Health of New England. Therefore, I can only base my opinion upon the records provided to me, as I no longer have access to the electronic medical records at these facilities. For this reason, I cannot confirm when I first began treating Ms. Paige nor can I provide any additional records that were not included." (Ex. 21, p. 1.) Petitioner has not suggested that she discussed her vaccination with Dr. Boudreau at any point prior to June of 2017. (ECF No. 72, p. 9 (citing Ex. 6, p. 25).)

⁷ There are handwritten notations on the time records indicating that petitioner was on the mobile unit on October 9th and that she was vaccinated on November 11th (Ex. 34, pp. 3, 5); however, Ms. Jones confirmed in her deposition that these notations were not contemporaneous, likely made in 2019, and were based on the vaccination record in petitioner's employee file. (Ex. 25, pp. 43-44, 46.)

On April 29, 2016, petitioner applied for Family Medical Leave Act ("FMLA") benefits based on a certification of healthcare provider by Dr. Boudreau. (Ex. 14, pp. 52-55.) Prompted to describe other relevant medical factors, Dr. Boudreau described petitioner's condition as "work up pending. Likely has transverse myelitis which is either idiopathic or secondary to MS. If it is secondary to MS, this will be a chronic illness." (*Id.* at 53.) Dr. Boudreau did not discuss petitioner's vaccination history. On May 3, 2016, petitioner was advised that her request for FMLA benefits was granted, applying to all leave taken from March 31, 2016 through June 5, 2016. (*Id.* at 27.)

Petitioner subsequently submitted further certifications by Dr. Boudreau in support of FMLA benefits dated June 16, 2016, and July 28, 2016. (Ex. 14, pp. 65-72.) In both certifications, Dr. Boudreau characterized petitioner's condition as secondary to cord compression from spinal stenosis and again did not reference petitioner's vaccination history. (*Id.* at 66, 70.)

Petitioner was subsequently advised on August 31, 2016, that her Family Medical Leave Act benefit had been exhausted. (Ex. 14, p. 16.) Her employer subsequently contacted Dr. Boudreau to discuss accommodations requested by petitioner; however, petitioner was later advised by letter dated October 26, 2016, that she was terminated effective immediately due to exhausting her medical leave. (*Id.* at 9, 13.) She was advised that if circumstances change in the future, she could reapply for any position for which she is qualified. (*Id.* at 9.)

C. As described in testimony

1. Petitioner's affidavits

As noted above, petitioner's first affidavit accompanying her petition indicated that she received her flu vaccination from her supervisor while operating a mobile health unit on October 9, 2015. (Ex. 8.) In this affidavit she indicated that her vaccination was documented two days later. (*Id.*)

In the context of further litigating her allegation that she was vaccinated on October 9, 2015, petitioner later filed a supplemental affidavit on June 28, 2019. (Ex. 15.) In her supplemental affidavit, petitioner stressed that October 9, 2015 was the only date that she worked on the mobile health unit and further indicated that she volunteered to work at the mobile health unit that day so that her supervisor would not have to work alone. (*Id.* at 1.) She explained that "[t]he patients that were vaccinated on the mobile health unit had their data input in to an electronic chart. As an employee, I did not have an electronic chart and the vaccination was not documented contemporaneously with its administration. Instead, it was recorded on a worksheet several weeks later." (*Id.*)

Petitioner further indicated that "I distinctly remember that I was going to be attending a Taj Mahal concert the following week, Friday, October 16, 2015 at the Garde Theater in New London, Connecticut. I was looking forward to this concert and

remember thinking I would surely be free of any residual effects from the vaccination in time for the concert." (*Id*.)

2. Petitioner's deposition

During her deposition, petitioner explained that she began working at Generations Family Health as a nurse case manager in October of 2012. (Ex. 24, p. 6.) Her regular duties were within the "Ryan White Program" (an HIV clinic). (*Id.*) During the period at issue, Nicole Jones was petitioner's direct supervisor. (*Id.* at 7.) Petitioner's regular duties within the Ryan White Program included, inter alia, vaccinating her patients and completing vaccine administration forms. (*Id.* at 32-34.) Petitioner recalled that employee flu vaccinations became mandatory beginning in 2014. (*Id.* at 53.) If an employee refused to be vaccinated by a certain date, that employee would have to wear a mask. (*Id.* at 11.) However, petitioner could not recall the date by which vaccination was required. (*Id.*)

Petitioner described working on the mobile health unit on one occasion, October 9, 2015. (*Id.* at 7-8.) On that date, the mobile unit went to a location known as "Pride's Corner" to provide flu vaccinations and informational pamphlets to migrant farm workers. (*Id.* at 8.) Ms. Jones and petitioner administered vaccinations while two others handed out the educational materials. (*Id.*) To petitioner's knowledge this is the only date that year that the mobile unit administered vaccinations. (*Id.* at 9.) She recalled the mobile unit being out from about 10:00AM to 1:00PM. (*Id.* at 12.)

Petitioner described the mobile health unit as a "motorhome" with two stations inside. (*Id.* at 9.) She confirmed that vaccinees were presented with a screening and consent form that she reviewed with them to obtain consent. (*Id.*) Asked specifically how vaccinations were recorded, she indicated "[t]here is a document that, that you fill out and they get a copy of it and we get one. Generations, it would be one for them and one for us to keep for our records." (*Id.*)

Petitioner described her own vaccination as follows:

So we could get a rush of, you know, influx of the workers coming to get their shots, and then there would be lulls. And so there weren't many people there, it started to thin out, and so we said, like, do you want to do it now, this would be a good time to do it, this would be. No one is here. And she [referring to Ms. Jones] proceed to give me my vaccine.

(*Id.* at 10.) Petitioner recalled this as occurring after lunch. (*Id.*) Petitioner noted that she was the only employee vaccinated at that time and further indicated that it would be unusual for Ms. Jones to administer a vaccine to her staff. (*Id.* at 10-11.)

However, during her deposition, petitioner also authenticated the vaccine administration record filed as Exhibit 1. (*Id.* at 16.) She confirmed her own signature on the document and confirmed that she completed the questionnaire portion of the

document. (*Id.*) Petitioner also confirmed that she marked the document as reflecting that the vaccine was administered at her employer's Willimantic work site and that she dated the document twice as November 11, 2015. (*Id.* at 17.) Petitioner indicated that all writing on the document above the heading "clinic use" is her writing and that all writing below that heading is Ms. Jones's. (*Id.* at 37.) She confirmed that she completed her portion of the form first and that she signed the document on November 11, 2015. (*Id.* at 17-18, 38.) She explained:

So, on the date that I received the flu shot, it was never documented, and my supervisor's job, as infection control, was to insure [sic.] that all the staff was vaccinated. So she stopped by my office one day, November 11, and said Sherri, we got to get documentation on that shot that I gave you. And I said, okay, no problem. So I began to fill it out, and she signed and completed it.

(Id. at 18.)

Asked how Ms. Jones knew which arm to document for administration, petitioner suggested that Ms. Jones would have asked her. Petitioner indicated she was confident she would not have received any vaccination in her dominant arm. (*Id.* at 39-40.) However, petitioner does not know how Ms. Jones determined the vaccine lot information and does not recall providing that information to her. (*Id.* at 40.)

Petitioner explained that at the time she shared an office with a coworker, Ingrid Aldridge, who may have been present at the time she completed this form. (*Id.* at 18, 53-54.) However, petitioner did not know whether she would have overheard her conversations with Ms. Jones about the vaccination record. (*Id.* at 53-54.)

Petitioner was asked whether she ever discussed with Ms. Jones "the difference in the dates that you received the vaccination and the difference in the date that this document was created." (*Id.* at 19.) She responded, "eventually," further indicating that:

[O]nce it was brought to my attention about the immunization, you know, the correlation of the flu shot and transverse myelitis, I called Generations to find out when my last flu shot was to see if it applied to me. And initially they had 2014 because this flu shot wasn't entered into my shot chart, but then when I got this form, you know, when I had this form it says, November 11th. So I called Nicole Jones and said that the date that my flu shot was documented and the day that it was actually done are two different dates, and I need proof of the date the vaccine was actually given.

(*Id.* at 19.) Petitioner described this interaction as culminating in the text message response discussed further below which she indicated she received in March of 2016. (*Id.* at 20-23.)

3. Ms. Jones's deposition

Ms. Jones confirmed that she has been the director of the Ryan White HIV program since June of 2015 and that she was responsible for supervising petitioner in 2015. (Ex. 25, pp. 11, 15.) She also confirmed that she and petitioner administered flu vaccinations to farm workers at Pride's Corner on one occasion on October 9, 2015. (*Id.* at 16-17.) Ms. Jones indicated that the vaccinations administered that day were documented strictly on paper and were entered into the electronic health record later. (*Id.* at 19.) Ms. Jones suggested that it was not until after the event that they realized the vaccinations needed to be entered into the electronic record "as given" rather than merely scanning the paper form. (*Id.* at 21-22.) This process was completed on November 2, 2015. (*Id.* at 22.)

Ms. Jones denied that she administered a flu vaccination to petitioner on October 9, 2011. (*Id.* at 22.) Rather, she indicated that she recalled giving petitioner her vaccination in November. (*Id.* at 22-23.) Asked if she had personal knowledge of the vaccination being given on November 11, she testified:

- A. I know it was November. I absolutely did not give it on the van.
- Q. Why are you sure that it was November?
- A. Because I am pretty sure it was getting closer to Thanksgiving, and we have a cutoff date for our employees that we like them to get the flu shot, and she was after that. And that is November 1st, and she was after that date.

(*Id.* at 23.) On later questioning, however, Ms. Jones could not specifically recall whether the vaccination deadline was November 1st in 2015. (*Id.* at 46-47.) She reasoned that the deadline would have been the same, but could only specifically recall that it had not changed in the prior three years. (*Id.* at 47.) Ms. Jones could not recall whether petitioner ever wore a mask in 2015. (*Id.*)

Ms. Jones testified that she vaccinated petitioner at the Willimantic clinic because petitioner had asked her to do so on that same day. No one else was present when petitioner was vaccinated. (*Id.* at 24.) Ms. Jones recalls petitioner being adamant that Ms. Jones administer the vaccine instead of another nurse, but did not know the reason why. (*Id.* at 24-25.) Administering vaccines is not a part of Ms. Jones's typical work function. (*Id.* at 34-35.)

Referring to petitioner's Exhibit 1, Ms. Jones confirmed her handwriting on the "clinic use" portion of the document, including her notation regarding the injection site, lack of any vaccine reaction, and the manufacturer and lot information. (*Id.* at 26-27.) She denied dating the document, but confirmed that she completed her portion of the form on the date indicated, which was the date of administration. (*Id.* at 27.) Ms. Jones agreed that petitioner completed her portion of the form first. (*Id.*) Petitioner signed and

dated the form in front of Ms. Jones and Ms. Jones subsequently took the document to human resources. (*Id.* at 28.) She confirmed that the type of employee immunization form used for petitioner's vaccination would not have been available on the mobile health unit. (*Id.* at 35-36.) Ms. Jones denied that she has ever had occasion to complete a vaccine administration form several weeks after administration. (*Id.* at 40.)

4. Ms. Aldridge's affidavit

Petitioner's former coworker, Ms. Ingrid Aldridge, submitted an affidavit in which she indicated in relevant part that:

Sometime after the Pride's Corner Clinic event, I recall Sherri Paige asking me to assist her in looking up the lot numbers for the vaccinations that were given at the Pride's Corner event. Sherri told me that she needed this information to fill out her own vaccine administration form. We joked that she was not good at using the computer. I do not recall the date of this conversation.

(Ex. 42, p. 1.) Ms. Aldridge is no longer employed at Generations Family Health. (Id.)

D. As evidenced by additional documents

1. E-mails produced by Nicole Jones at her deposition

In connection with her deposition, Ms. Jones produced several separate e-mail chains which were marked as Deposition Exhibits 9-12 and petitioner's Exhibits 36-39. She explained that these e-mails were gathered by searching petitioner's name within her e-mail history for the period from June of 2015 to June of 2016. (Ex. 25, p. 41.) They are not representative of the entirety of her e-mail communications with petitioner. (*Id.*) Not all of the e-mails are between petitioner and Ms. Jones.

The first set of e-mails marked as Exhibit 36 reflect informal exchanges between petitioner and Ms. Jones from October to December of 2016 regarding adjustments to petitioner's working hours due to illness and sick leave. In one exchange, petitioner wrote on November 2, 2015, in apparent reference to the Pride's Corner vaccination event:

COLEY JONES, I THINK YOU OWE ME YOUR LIFE AND LUNCH! THOSE DARNED FLU SHOTS OMG. I SHALL NOT VOLUNTEER NEXT YEAR UNLESS WE TAKE A LAPTOP AND DOCUMMENT THERE!!!!! UGH!!!!!!!! JK, IT WAS VERY TIME CONSUMING BUT NOT DIFFICULT

(Ex. 36, p. 2.) The majority of the remaining e-mails pertain to petitioner's separation from Generations Family Health and her follow up communication seeking documents related to her vaccination, but are not illuminating as to the details of petitioner's vaccination. (Exs. 37-39.)

2. <u>Text message by Nicole Jones</u>

Petitioner also filed a single page document that appears to be a screen capture from a cell phone which appears under a separate heading indicating a date of June 30, 2017. (Ex. 13.) The text is from "Coley Jones" and states:

Sorry it's taken a while to get back to you. Your Flu shot documentation from 10/9/15 was in your HR file since it was done as an employee not a patient. HR has sent it to your last address on file with them. You can ask medical records to have it put into your chart if needed, but HR nor I can put it in your chart since it wasn't given during a visit. If you need something else give me a call at work . . . Thanks!

(Ex. 13, p. 1.) During her deposition, Ms. Jones confirmed that the telephone number reflected on the text message is her telephone number; however, she does not recall when she sent the text. (Ex. 25, p. 28-29.) She denied that the text message is an acknowledgement that she vaccinated petitioner on October 9, 2015, suggesting she would not have had access to the vaccination record and would have merely repeated back whatever date petitioner had stated in requesting her record. (*Id.* at 29-32.)

Petitioner indicated during her testimony that June 30, 2017, is not the date that she received the text message and questioned whether it might be the date on which she sent it to her counsel. (Ex. 24, p. 46.) She indicated that to the best of her recollection, she received this message in March of 2016; however, she had also previously testified that she could not recall when she sent the text that prompted this response. (*Id.* at 21-23.) Notably, petitioner described the entire course of communication leading up to this text message as being prompted by her discovering the possible connection between her vaccination and transverse myelitis. (*Id.* at 19.) As discussed above, petitioner is first recorded as having discussed this with her physicians in June of 2017 (Ex. 6, p. 25), which is potentially consistent with the June 30, 2017 heading accompanying the text message (Ex. 13).

3. Generations Family Health response to petitioner's interrogatories

Finally, Generations Family Health confirmed in written interrogatory responses that a search of their records indicates that 1,952 individuals were vaccinated using the flu lot listed on petitioner's immunization record between September 21, 2015, and June 24, 2016, including doses administered on both October 9, 2015, and November 11, 2015. (Ex. 41, p. 1.) However, all individuals vaccinated by the mobile health clinic on October 9, 2015, were vaccinated using doses from a different lot. (*Id.*) This information is confirmed both by individual chart entries in the provider's electronic health records ("Greenway Integrity" suite) as well as signed consent forms scanned into each individual's chart. (*Id.*)

III. Legal Standard

Petitioner has the burden of demonstrating the facts necessary for entitlement to an award by a "preponderance of the evidence." § 300aa-12(a)(1)(A). Under that standard, the existence of a fact must be shown to be "more probable than its nonexistence." *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring). Moreover, the Vaccine Act states that "[t]he special master or court may not make such a finding [of eligibility and compensation] based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." § 300aa-13(a)(1). Nonetheless, special masters are not bound by the reports, summaries, or conclusions contained in the medical records. § 300aa-13(b)(1). Rather, the special master must consider the entire record. *Id*.

The fact of a vaccination need not itself be proven by medical records or medical opinion. See, e.g. Wonish v. Sec'y of Health & Human Servs., No. 90-667V, 1991 WL 83959, at *4 (Cl. Ct. Spec. Mstr. May 6, 1991)(stating with regard to § 300aa-13(a)(1) that "it seems obvious then that not all elements must be established by medical evidence" and that "vaccination is an event that in ordinary litigation could be established by lay testimony. Medical expertise is not typically required.") Nor, for that matter, does it necessarily have to be evidenced by contemporaneous documentation. See, e.g. Centmehaiey v. Sec'y of Health & Human Servs., 32 Fed. Cl. 612, 621 (1995), (noting that "the lack of contemporaneous documentary proof of vaccination, however, does not necessarily bar recovery."), aff'd 73 F. 3d 381 (Fed. Cir. 1995); see also Woodson v. Sec'y of Health & Human Servs., No. 91-263V, 1992 WL 59707, at *2 (Fed. Cl. Spec. Mstr. Mar. 5, 1992)(noting that "[t]he petition should not be dismissed as a matter of law, merely because there is no documentary evidence that the vaccination took place and [petitioner] is the only witness claiming personal knowledge of the vaccination. Her testimony on this point must be weighed in the context of the entire record.").

Importantly, however, the instant case is not one of a merely missing or inadequate vaccination record. Rather, in this case a facially valid vaccination record does exist that is contradictory to petitioner's allegation. *Accord Muller v. Sec'y of Health & Human Servs.*, No. 14-801, 2017 WL 2334031, at *8 (Fed. Cl. Spec. Mstr. Feb. 27, 2017) (declining to accept testimonial evidence over a contemporaneous medical record regarding the date of vaccination).

In that regard, medical records do ordinarily "warrant consideration as trustworthy evidence." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed.Cir.1993). Where subsequent testimony conflicts with contemporaneous medical records, special masters frequently accord more weight to the medical records. *See, e.g., Reusser v. Sec'y of Health & Human Servs.*, 28 Fed. Cl. 516, 523 (1993) ("[W]ritten documentation recorded by a disinterested person at or soon after the event at issue is generally more reliable than the recollection of a party to a lawsuit many years later."); *See also Vergara v. Sec'y of Health & Human Servs.*, 08-882V, 2014 WL 2795491, *4 (Fed. Cl. Spec. Mstr. July 17, 2014) ("Special Masters frequently accord

more weight to contemporaneously-recorded medical symptoms than those recorded later in medical histories, affidavits, or trial testimony.").

Special masters are cautioned against favoring contemporaneous records "reflexively" and must not overemphasize individual records at the expense of a comprehensive evaluation of the entire record. *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 539-40 (2011). "Medical records are only as accurate as the person providing the information." *Parcells v. Sec'y of Health & Human Servs.*, No. 03-1192V, 2006 WL 2252749, at *2 (Fed. Cl. Spec. Mstr. July 18, 2006). However, "the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance." *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (Fed. Cl. 1991), *aff'd* 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992).

There are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. Campbell v. Sec'y of Health & Human Servs., 69 Fed.Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); Lowrie v. Sec'y of Health & Human Servs., No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting Murphy, 23 Cl.Ct. at 733). However, when witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." Sanchez v. Sec'y of Health & Human Servs., No. 11-685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013 (citing Blutstein v. Sec'y of Health & Human Servs., No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)), mot. for rev. denied, 142 Fed. Cl. 247, 251-52 (2019), vacated on other grounds and remanded, 809 Fed. Appx. 843 (Fed Cir. 2020).

IV. Party Contentions

Although petitioner acknowledges the importance of contemporaneous medical records, she notes that special masters are required to weigh medical records against other evidence, including oral testimony. (ECF No. 72, pp. 7-8.) She further stresses, as noted above, that it is within the special master's discretion to weigh other circumstantial evidence more heavily than contemporaneous medical records, especially with regard to the fact of a vaccination having occurred. (*Id.* at 8 (citing *Brown v. Sec'y of Health & Human Servs.*, 18 Cl. Ct. 834 (1989), *rev'd on other grounds*, 920 F.2d 918 (Fed. Cir. 1990)).)

In her motion, petitioner urges consideration of four circumstantial factors. First, the evidence shows that the vaccinations administered at the mobile health clinic on

October 9, 2015 were not contemporaneously documented.⁸ (*Id.* at 8-9.) Second, if petitioner had not been vaccinated by November 1, 2015, then she would have faced a requirement to wear a mask when having patient contact; however, there is no evidence that she wore a mask at that time.⁹ (*Id.* at 9.) Third, petitioner did ultimately report to her neurologist that her symptoms began in October of 2015, which she indicated at that time was one-week after her influenza vaccination. (*Id.* at 9 (citing Ex. 6, p. 25).) And, fourth, petitioner specifically recalled that she had received her vaccination prior to a specific concert she attended on October 16, 2015, which is also when she placed onset of her symptoms. (*Id.*)

In response, respondent contends that petitioner's testimony was inconsistent and her recollection that she was vaccinated on October 9, 2015, uncorroborated. (ECF No. 73, p. 6.) Respondent also stresses that petitioner did not associate onset of her injury to her vaccination when speaking with her physicians until18 months after the fact. (*Id.* at 8.) Respondent further contends that petitioner has not provided a cogent explanation for why she signed and dated an incorrect vaccination record. (*Id.* at 8.)

Finally, respondent also notes that petitioner's medical records include some evidence that she began experiencing memory problems and cognitive issues prior to completing her sworn statements in this case. (*Id.* at 8-9 (citing Ex. 4, p. 943, 948; Ex. 7 pp. 1-2.) Respondent indicates that petitioner's recollections include a "confusing premise." That is, petitioner indicates she was not aware her record was incorrect until preparing for this litigation despite contending she has a detailed and accurate recollection of when and how the record was created. (*Id.* at 9.)

V. Discussion

As explained above, the record evidence in this case includes a facially valid and complete vaccine administration form identifying November 11, 2015 as the date of

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⁸ Petitioner's suggestion that these vaccinations were not contemporaneously documented is not strictly accurate. Both petitioner and Ms. Jones testified that vaccine administration records were created for patients at the time of vaccination. (Ex. 24, p. 9; Ex. 25, p. 19.) However, it was later discovered that the administrations had to be additionally documented in a different, electronic, format. (Ex. 25, pp 21-22.)

⁹ Notably, however, although petitioner testified that masks were required for unvaccinated employees beginning in 2014, she was never asked whether she was ever required to wear a mask nor did she otherwise at any point deny wearing a mask. (Ex. 24.) In any event, Ms. Jones offered testimony that has suggested that enforcement of this requirement may have been less than complete. Specifically, she indicated at the time of her deposition that the requirement "is more enforced now." (Ex. 25, p. 32.) She noted that it "is something we have gotten better at," explaining that "our vaccination rate was only 60 percent last year, and it is at 90 percent this year." (*Id.*) Ms. Jones was unaware of any specific tracking system for employee vaccination compliance during 2015. (*Id.* at 33.) Ms. Jones could not recall whether petitioner ever wore a mask in 2015. (*Id.* at 47.)

¹⁰ Although petitioner indicated that she initially contacted her employer to confirm the date of her prior vaccination, a close reading of petitioner's testimony does not necessarily reveal her to have indicated that she was surprised that she was provided an incorrectly dated vaccination record. (Ex. 24, p. 19-20.) Petitioner's testimony focused on her need to prove the October 9, 2015 vaccination allegation. She did not actually express that she was confused by the discrepancy.

vaccination at issue. (Ex. 1.) This document is styled as "Generations Family Health Center, Inc. EMPLOYEE INFLUENZA IMMUNIZTION" and the employment records subpoenaed by petitioner also appear to reflect that this record was kept in the ordinary course as part of petitioner's employee file. (Ex. 14, p. 5; Ex. 16, p. 8; Ex. 1.) This document is signed by both petitioner and Ms. Jones, the person who administered the vaccination. (*Id.*) Moreover, both Ms. Jones and petitioner further confirmed in testimony that this record was completed on the date indicated on the form. (Ex. 24, pp. 17-18, 38; Ex. 25, pp. 26-27.) Additionally, petitioner confirmed her signature on the document, which is itself also dated November 11, 2015. (Ex. 24, p. 16.) In response to petitioner's inquiry, Generations Family Health confirmed via interrogatory response that the vaccine lot listed on this administration record is distinct from the lot used for vaccinations at the mobile health clinic on October 9, 2015, but is consistent with the lot used by Generations Family Health for vaccinations on a wide range of dates throughout the 2015-2016 influenza season, including November 11, 2015. (Ex. 41, p. 1.)

Despite significant efforts seeking to investigate the circumstances of petitioner's 2015 flu vaccination, petitioner was unable to discover any significant evidence, apart from her own testimony, contradicting her vaccination record. Moreover, no error or omission is evident on the face of the document. Accordingly, in light of the above-discussed legal standard, petitioner's vaccine administration record is entitled to substantial weight. Petitioner, of course, urges that her testimony that she instead received her vaccination on October 9, 2015, should overcome the weight of this record. And, to be sure, petitioner's testimony did include a seemingly clear recollection of having received her vaccination on October 9, 2015. (Ex. 24, pp. 7-10.) However, although it is possible for persuasive testimony to overcome the weight afforded contemporaneous medical records, there are several issues with petitioner's testimony. Accordingly, petitioner's account is not sufficiently reliable to challenge her facially valid vaccine administration record.

First, the arguments advanced in petitioner's motion are unavailing. The fact that the vaccinations administered by the mobile health unit on October 9, 2015 were not correctly documented on site does not provide any significant support for petitioner's assertion that she was among those vaccinated. Nor does the absence of evidence she wore a mask or her recollection of attending a concert point to any meaningful corroboration. (See also n. 9, supra.) Rather, contrary to the arguments raised in petitioner's motion, her account remains both uncorroborated and contradicted by other record evidence.

Ms. Jones, the only available witness who was present with petitioner on both October 9, 2015 and November 11, 2015, disputes petitioner's recollection that she was vaccinated on October 9, 2015, and separately testifies that she does recall vaccinating petitioner in November of 2015 at the Willimantic worksite documented on the vaccine administration record. (Ex. 25, pp. 22-24.) Petitioner testified that Ms. Aldridge may have witnessed the creation of her vaccination record on November 11, 2015 (Ex. 24, pp. 18, 53-54); however, Ms. Aldridge's affidavit did not support petitioner's recollection

of her interaction with Ms. Jones (Ex. 42). Rather, Ms. Aldridge recalled only that she assisted petitioner in looking up the lot numbers for the vaccinations given by the mobile health unit. (Ex. 42.) Although Ms. Aldridge indicated that "Sherri told me that she needed this information to fill out her own vaccine administration form" (Ex. 42), as noted above, petitioner's own vaccination record was completed using a lot number different than what was administered by the mobile health unit (*compare* Ex. 1 and Ex. 41). Moreover, petitioner testified that she did not recall providing vaccine lot information to Ms. Jones for her own administration record. (Ex. 24, p. 40.) Instead, evidence shows that during the period at issue petitioner was involved in early November in an effort to retroactively ensure proper electronic logging of the vaccine administrations performed at the mobile health clinic on October 9, 2015. (Ex. 25, pp. 21-22; Ex. 36, p. 2.) Especially in light of the lot number included on her own vaccination record, this provides a more likely explanation for her interaction with Ms. Aldridge.

Moreover, as respondent notes in his motion response, petitioner did not initially discuss the possible relationship between her vaccination and her injury with her physicians and did not raise that possibility until 18 months later. (Ex. 6, p. 30.) Accordingly, petitioner's *contemporaneous* medical records also fail to corroborate her recollection of the date of her vaccination. The only possible piece of corroborating evidence is the text message in which Ms. Jones purportedly identified the date of petitioner's vaccination as "10/9/15." (Ex. 13.) However, Ms. Jones denied that the text was an acknowledgement of petitioner's correct vaccination date and testified that she did not have petitioner's record at that time and merely repeated the date stated by petitioner. (Ex. 25, pp 29-32.)

Second, other aspects of petitioner's testimony are not clear and consistent. As respondent noted, in her first affidavit petitioner initially recalled that her vaccination record was created only two days after she was vaccinated at the mobile health clinic whereas in her second affidavit she indicated the vaccination was recorded weeks later. (Ex. 8, p. 1; Ex. 15, p. 1.) More significantly, in her second affidavit, petitioner indicated that the specific reason her vaccination was not recorded as of October 9, 2015 was that the patient vaccinations administered at the mobile health unit that day were documented in electronic patient charts while as an employee she did not have an electronic chart. (Ex. 15, p. 1.) In her deposition, however, she testified that the mobile clinic used paper records. (Ex. 24, pp. 9-10,35.) In fact, in her motion petitioner stresses the fact of a contemporaneous e-mail in which petitioner complained of the

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¹¹ During her deposition, petitioner offered unclear testimony regarding the first affidavit. When asked if she drafted the affidavit, she initially indicated "yes." (Ex. 24, pp. 41-42.) However, she then noted some details of the affidavit and indicated "I wouldn't have known how to compile this." (*Id.* at 42.) Respondent's counsel specifically drew petitioner's attention to the specific statement in the affidavit that petitioner's vaccination was documented two days later. Asked if she wrote that specific statement, petitioner indicated "I don't believe I did." (*Id.*) Asked if she was ever under the impression that her vaccination was documented on October 11, 2015, petitioner responded "No." (*Id.* at 42-43.) Nonetheless, she acknowledged that the document was sworn and subscribed with her signature before a notary. (*Id.* at 43.)

lack of a laptop to document patient vaccinations on site. (ECF No. 72, p. 8 (citing Ex. 36, p. 2).) Although Ms. Jones testified that the specific employee immunization forms were not available on the mobile unit (Ex. 25, pp. 35-36), nothing in the record suggests that petitioner's vaccination could not have been documented for her employee file using a standard vaccine administration form. Thus, this inconsistency directly implicates the rationale underlying petitioner's description of events. Petitioner also offered confused testimony with regard to what file, and in what format, her prior 2014 influenza vaccination would have been documented. ¹² (Ex. 24, pp. 44, 54.)

Third, petitioner's testimony creates a credibility issue in itself due to the particular circumstances of this case. As discussed during her testimony, petitioner is a nurse experienced in administering vaccinations and completing administration records, received her vaccination in the context of her employment, and allegedly participated in the after-the-fact creation of her own vaccination record. (Ex. 24, pp. 16-17, 37-38.) Indeed, petitioner confirmed during her testimony that she dated her vaccination record herself. (*Id.* at 17.) Thus, in order to accept her own account of her vaccination as credible, I would also have to accept that she either mistakenly or willfully completed and signed a vaccination record falsely identifying the date of her vaccination. Yet, petitioner did not provide any explanation or rationale as to why her vaccination record, even if circumstances caused it to be created belatedly, would have reflected this incorrect information.

Petitioner was asked during the deposition whether she asked Ms. Jones at any point to fill out a vaccine administration record. She responded: "I did not. She administered the vaccine. It is her role to document her work. And she is my supervisor. And as infection control, that is all her job, to make sure that the shots were administer [sic.] and there is documentation thereof. So it wouldn't have been my place to, sort of, keep track of her work." (Ex. 24, p. 50.) This provides some rationale as to timing; however, petitioner confirmed in her testimony that when the time did come to complete the administration record she completed her portion of the form – which included the date in two locations – before Ms. Jones completed the clinic use portion. (*Id.* at 17-18, 38.) She also testified that she did not discuss the date of her vaccination with Ms. Jones until much later when she began to connect her medical condition to her vaccination and received a copy of her vaccination record. (*Id.* at 19.) Accordingly, her testimony indicates that she documented the November 11, 2015 administration date on her own initiative with no explanation for why she would have initially completed the form incorrectly.

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¹² Initially, petitioner testified that she knew that her 2014 flu vaccine was documented in her patient chart, because it would have been entered into her electronic patient chart at the time of administration. (Ex. 24, p. 44.) Later, she indicated the vaccination was not administered to her as a patient and would have been done "very much the same as what we did with Nicole Jones." (*Id.* at 54.)

VI. Conclusion

In light of all of the above, there is preponderant evidence that petitioner received an influenza vaccination on November 11, 2015. There is not preponderant evidence that petitioner received an influenza vaccination on October 9, 2015.

IT IS SO ORDERED.

<u>s/Daniel T. Horner</u> Daniel T. Horner Special Master